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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,485	09/15/2000	Nobuya Sato	197129US0PCT	7267

22850 7590 06/17/2002

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EXAMINER

GHALI, ISIS A D

ART UNIT PAPER NUMBER

1615

DATE MAILED: 06/17/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/623,485

Applicant(s)

SATO ET AL.

Examiner

Isis Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 March 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 11-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

The receipt is acknowledged of applicants' request for extension of time and amendment A, both filed 3/20/2002; and IDS, filed 5/16/2002.

### ***Response to Amendment***

1. Newly submitted claims 11-23 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the new claims are directed to method of making and method of use that were not previously presented.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 11-23 are withdrawn from consideration.

**Claims 1-10 are included in the prosecution.**

**The following new ground of rejections are necessitated by applicants' amendment A, in Paper No. 6:**

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 10 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The acronyms "EPDM" and "EPM" are not permitted in the claims.

***Response to Arguments***

4. Applicant's arguments filed 3/20/2002 have been fully considered but they are not persuasive.

**The standing rejections are as follows:**

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US 4,122,158 ('158), US 4,344,431 ('431), and US 6,063,397 ('397), each by itself or in combination.

US '158 teaches a method and composition for topical application to the skin comprising active agent in an amount of 0.001 to 30% and a fabric carrier of polyolefin polymer. See abstract; col.2, lines 17-60; col.3, lines 56-68; col.3, lines 1-5; col.6, lines 52-67; col.7, lines 10-15.

US '431 discloses a polymeric article for dispersing drugs to the skin surface comprising polymeric material such as polyolefin (thermoplastic resin); polypropylene and polyesters (hard segment of thermoplastic elastomer) and; polyethylene (soft

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segment elastomer); and combination of these. and a drug such as corticosteroids (anti-inflammatory drugs). The article further comprises a drug in an amount ranging from 0.5 to 50% by weight. The article can be shaped as a film. See the abstract; col.2, lines 45-46, 64-67; col.3, lines 62-68; col.4, lines 1-2; col.6, line 59; col.6, lines 57-64; col.7, lines 47-50; col.9, lines 3-7.

US '397 is teaching a personal care product comprising a substrate in form of sheet and conditioning agent (moisturizer) in amount from about 3-99%. The sheet comprises polyolefin; polypropylene; polyethylene; and mixtures thereof. The reference also disclosed the active agent as anti-wrinkles and anti-inflammatory. The reference See abstract; col.3, lines 33-37; col.5, lines 18-63; col.7, lines 25-26; col.17, lines 15-16, 59; col.18, line 1; col.25, lines 16, 26-30; col.26, lines 52-56.

The references do not teach the amount of the polyolefin. It is within the skill in the art to select optimal parameters such as ratios and weight percents of components in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980). Therefore, the weight percent of the polyolefin instantly claimed is not considered critical absent evidence showing unexpected and superior results.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a sheet material comprising thermoplastic polymers and active agent and adjust the amount of the ingredients in order to achieve a beneficial effect with reasonable expectation of success of the delivered sheet in providing useful medical ingredient with comfortable sensation during use.

**Applicants' arguments:**

- US '158 aimed at solving the problem of treating burns through the release of the active agents and US '431 disclosed a composition useful for subcutaneous devices.
- US '158, US '431 and US '397 do not describe a composition containing a modulus of cN/10 mm when the sheet is stretched by 50%.

**Examiner's position is:**

- The claims are directed to an article, and the components of the article are disclosed by the all the cited references. The future intended use has no patentable significance in product claims. Regarding the US '431, the reference disclosed application of the composition on the skin, col.7, lines 47-50.
- The references disclosed the same components, thus, it is expected to have the same properties such as elasticity. It is also within the skill in the art to adjust the amount of the thermoplastic polymer in order to achieve a desired modulus according to the particular need.

***Conclusion***

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali  
Examiner  
Art Unit 1615

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600